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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,599	11/20/2003	Lars Eric Sundstrom	MAR37 P-314A	3116

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EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,599	SUNDSTROM ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *33-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

Applicants' election of Group I is acknowledged, as are the elected species. Claims 1-32 are examined in this Office action; claims 33-43 are withdrawn from consideration.

✧

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is also objected to because a reference is made to a figure 1 in several locations (see, e.g., page 33, line 7; page 32, lines 7 and 17). However, no drawing was filed with the application.

✧

35 U.S.C. §101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter or any new and useful improvement therof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-32 are rejected under 35 USC §101 because the claimed invention is not supported by a well-established utility.

The claims are drawn to a method of "protecting" any and all neurons from any damage that might result from ischemia or some other traumatic event. This term implies that 100% of all neurons and neuronal cell types within a given mammal will be completely unaffected by an ischemic event, no matter how severe, or how long the oxygen deprivation might be. If, in a

given experiment, 1% of the neurons of one particular cell type exhibited any signs of membrane damage or reduced activity, such a result would constitute evidence that protection had not been achieved. Applicants own data, in fact, demonstrates that the disclosed compounds fail to protect 100% of the CA1 neuronal cells. Further, applicants have made no attempt to determine whether other neuronal cell types are affected one way or another by the compounds. It is suggested that claim language be adopted which does not assert 100% efficacy in 100% of neuronal cells. Perhaps the phrase *reducing the incidence of neuronal cell death* could be used in some way.

Claims 1-32 are also rejected under 35 USC §112 first paragraph. Specifically, since the claimed invention is not supported by a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

✧

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-32 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is lacking for the claimed invention. As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

Applicants have conducted experiments which show some effect of Arg-Sp on propidium iodide uptake in CA1 cells *in vitro*. The data presented are for *in vitro* experiments. An *in vivo* experiment is described on page 31, line 13+, but no data is presented. Although applicants have attempted to blur the lines between the *in vitro* and *in vivo* experiments, the data presented is from *in vitro* experiments. In Morrison (*British journal of pharmacology* **137** (8) 1255-68, 2002), an *in vivo* experiment is briefly described (page 1263, col 2, last paragraph). Following administration of Arg-Sp at a time 15 minutes prior to induction of ischemia, some reduction of neuronal cell loss was observed in the CA1 region. The compound was not particularly effective in the CA3 region, although that is a secondary point. The primary point is that the only *in vivo* experiment conducted was with a compound that was administered prior to the ischemic event. Attempting to extrapolate from results obtained by

administering the compound before ischemia to a therapeutic method that comprises administration after ischemia leads to "unpredictable" results. . This matter is discussed, for example, in Jonas (*Annals NY Acad Sci* 939, 257-67, 2001). The claims encompass the possibility of administering the compounds several days after the ischemic insult has occurred. And for that matter, the claims encompass the possibility of administering the compound several weeks before the incidence of ischemia. Enablement is lacking for these possibilities. And certainly, enablement is entirely lacking for a claim that recites "protection" against neuronal damage. Accordingly, "undue experimentation" would be required to practice the claimed invention.

There is, nevertheless, an argument to be made for a claim that is drawn to a method of reducing the incidence of neuronal cell death.

✧

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1600